

**Application No. 10/083707**  
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**Amendment**  
**Attorney Docket No. S63.2R-10308-US01**

### **Remarks**

This Amendment After Final is in response to the Final Office Action dated **October 26, 2004**, wherein claims 17-19, 21 and 35-40 were objected to as well as rejected. In the Final Office Action claims 17-19, 21 and 35-40 were rejected under 35 U.S.C. §112, first and second paragraph; claims 17-19, 21 and 35-40 were also rejected under 35 U.S.C. §102(e) as being anticipated by U.S. 6,325,826 to Vardi et al (hereinafter: Vardi); claims 17-19, 21 and 35-38 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. 6,494,905 to Zedler et al (hereinafter: Zedler); and claims 17-19, 21 and 35-40 were rejected under 35 U.S.C. §103(a) as being obvious over Vardi in view of U.S. 6,165,195 to Wilson et al (hereinafter: Wilson).

The following comments are presented in the same order, and with paragraph headings and numbers corresponding to the Final Office Action.

### **Claim Objections**

1. In the Final Office Action claims 17-19, 21 and 35-40 were objected to because the preamble to the claims should be "An apparatus comprising" instead of "A system for deploying a bifurcated stent assembly." In response, Applicants note that independent claims 17 has been amended to affirmatively recite "a bifurcated stent" as well as "only a single catheter". Because the claims recite a single catheter and a bifurcated stent it is appropriate to describe the invention in the preamble of the claim as a "system". In light of the above Applicants respectfully request withdrawal of the objection.

### **Response to Amendment**

2. In the Final Office Action the Amendment of August 3, 2004 was objected to under 35 U.S.C. §132 because it introduced new matter into the disclosure. More specifically, the Final Office Action asserts that "a system for deploying a bifurcated stent assembly with only a single catheter having a single balloon" is not supported by the original disclosure.

Applicants respectfully disagree and direct the Examiner to FIGs. 1-3 as well as to page 11, lines 8-23 of the Application as originally filed. The portion of the specification cited above does not describe multiple catheters or balloons as asserted in the Final Office Action but rather describes an embodiment of the invention wherein a catheter having a unique balloon 30,

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shown in FIG. 3, is used to deploy the bifurcated stent 10 shown in FIGs. 1 and 2. As the Application fully discloses the manner and mechanism for the deployment of both the stent body 12 as well as the scaffold 14 of the stent 10 using a single balloon 30 of a catheter the amendments to the claims of August 3, 2004 are fully supported. In light of the above withdrawal of the objection is respectfully requested.

**Claim Rejections – 35 U.S.C. §112**

3-4. In the Final Office Action claims 17-19, 21, and 35-40 were rejected under §112, first paragraph as containing new matter.

As discussed above, all of the elements of the instant claims are fully supported by the Application as originally filed (see FIGs. 1-3 and page 11, lines 8-23). The rejection is respectfully traversed.

5-7. In the Final Office Action claims 17-19, 21, and 35-40 were rejected under §112, second paragraph. More specifically, the Final Office Action notes asserts that it is unclear whether a first and second stent bodies are included or excluded from the system. As discussed above, independent claim 17 has been amended to specifically recite the inclusion of a bifurcated stent in the system. In addition the claims have been clarified to remove recitation of first and second stent bodies. The rejection is therefore respectfully traversed.

**Claim Rejections – 35 U.S.C. §102**

8-9. In the Final Office Action claims 17-19, 21 and 35-40 were rejected under §102(e) as being anticipated by Vardi.

Vardi does not teach or suggest all of the elements of the instant claims. More specifically, Vardi fails to provide for a system wherein only a single catheter is utilized in the deployment of a bifurcated stent as instant claim 17 describes. In the embodiment depicted in FIGs. 7-9 of Vardi the main stent 40 is positioned in the vessel by guidewire 20 and catheter 44, while the expandable portion 38 is expanded into the branch vessel by the balloon 25 of a branch catheter 54. Unlike the system described in the instant claims, Vardi makes clear that *multiple* catheters are utilized to fully deploy the stent 40 *and* the expandable portion 38. Nowhere does Vardi teach or suggest a system wherein a single catheter having a single balloon is used to

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deploy a stent and scaffold as the instant claims describe. As a result the rejection is respectfully overcome.

10. In the Final Office Action claims 17-19, 21 and 35-38 were rejected under §102(e) as being anticipated by Zedler. Zedler clearly describes a catheter having two balloons 1.1 and 1.2. Though, the balloons of Zedler may be inflated simultaneously it is clear that the balloons are separate and distinct balloons as each is provided with a separate fill opening 3.1 and 3.2 respectively. The provision of two balloons is in contrast to the recitation of instant claim 17 wherein a single balloon is used to deploy the stent wall and the scaffold. As a result the rejection is respectfully overcome.

**Claim Rejections – 35 U.S.C. §103**

11-12. In the Final Office Action claims 17-19, 21 and 35-40 were rejected under §103(a) as being obvious over Vardi and Wilson.

There is no motivation to combine Vardi and Wilson in the manner proposed in the Final Office Action

As is clear from the disclosures the systems of Vardi and Wilson are distinct systems that are attempting to solve different problems. In the embodiment of FIGs. 7-9 of Vardi a system is depicted which employs a substantially tubular stent body 40 having an expandable side structure 38 that is expanded from the main stent body 40 after the main stent body has been positioned and been deployed in the vessel. This type of sequential deployment is in contrast to Wilson, wherein a branched balloon, such as is shown in FIGs. 27-33 is used to deploy both arms of a branched stent 100 simultaneously (see column 23, lines 13-28). Vardi and Wilson, alone or in combination, provide no teaching or suggestion that the branched balloon of Wilson could be utilized for the type of sequential deployment that Vardi requires in order to properly deploy the Vardi stent. As such there can be no motivation to attempt to combine the single branched balloon of Wilson into the Vardi system as proposed in the Final Office Action. As a result the §103 rejection is respectfully overcome.

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**Conclusion**

Claims 17, 19 and 39-44 are pending. Claims 1-16, 18, and 20-38 are cancelled without prejudice or disclaimer. Claims 17, 39 and 40 have been amended to clarify that the stent is a part of the system claimed. New and dependent claims 41-44 have been added to describe features of the invention such as are shown in FIGs. 1-3 and fully described in the specification on page 11 lines 8-23. No new matter has been added.

In view of the foregoing it is believed that the present application, with claims 17, 19 and 39-44 is in condition for allowance. Early action to that effect is earnestly solicited.

Respectfully submitted,

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